



United States
Department of
Agriculture

June 5, 2000

Marketing and
Regulatory
Programs

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 00-07

Animal and Plant
Health Inspection
Service

Subject: Standard Reference Bacterin, ERB-5

Veterinary Services

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

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PURPOSE

This notice informs all manufacturers of products containing *Erysipelothrix Rhusiopathiae* Bacterin of a change in procedures when conducting potency tests according to 9 CFR 113.119 using the current *Erysipelothrix rhusiopathiae* Standard Reference Bacterin, ERB-5.

BACKGROUND

The Center for Veterinary Biologics (CVB) established the current *Erysipelothrix rhusiopathiae* Standard Reference Bacterin, ERB-5, in 1996. At that time, results of efficacy studies in swine were used to establish the use of ERB-5 undiluted as the Standard in the mouse challenge potency assay in 9 CFR 113.119. We have evaluated new data from testing by licensed manufacturers and the CVB-Laboratory and have determined that undiluted ERB-5 has a higher potency than that required to protect pigs when using the swine challenge model described in 9 CFR 113.67.

ACTION

In light of these data, CVB has determined that ERB-5 at a dilution of 1:2 should be used as the Standard in the mouse challenge potency test outlined in 9 CFR 113.119. Therefore, when conducting this test using ERB-5 as the Standard, firms should change the initial dilution of the Standard from undiluted to a 1:2 dilution.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics



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